PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
48530		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/IB00/01260	05/07/2000	05/07/1999
International Patent Classification (IPC) or national classification and IPC A61K51/00		
Applicant ORTIZ ARMUA, Pedro		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
   - VI ☒ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
05/02/2001	23.10.2001
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Greif, G Telephone No. +49 89 2399 8659

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/IB00/01260

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:
Description, pages:

1-8 as originally filed

Claims, No.:

1-23 as originally filed

Sequence listing part of the description, pages:

1, as originally filed

, filed with the demand

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☒ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:

☐ the claims, Nos.:

☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 3,4, 12-22.

because:

☒ the said international application, or the said claims Nos. 12-22 with respect to IA only (see separate sheet Item III, paragraph 2 and Item V, paragraph 5) relate to the following subject matter which does not require an international preliminary examination (*specify*):
see separate sheet

☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 3, 4 (see separate sheet Item III, paragraph 2) are so unclear that no meaningful opinion could be formed (*specify*):
see separate sheet

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the said claims Nos. .

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	10, 11, 15-20, 22
	No:	Claims	1-2, 5-9, 12-14, 21, 23
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1, 2, 5-23
Industrial applicability (IA)	Yes:	Claims	1-11, 23
	No:	Claims	

2. Citations and explanations
see separate sheet

VI. Certain documents cited

1. Certain published documents (Rule 70.10)

and / or

2. Non-written disclosures (Rule 70.9)

see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. Claims 12-22 relate to a method of treatment or diagnosis of a human or animal body and therefore relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(i) PCT).

2. Claims 3 and 4 do not meet the requirements of Article 6 PCT in that the matter for which protection is sought is not clearly defined. The claims attempt to define the subject-matter in terms of the result to be achieved ("capable of performing a specific binding in the salivary glands...") which merely amounts to a statement of the underlying problem. In order to remove this objections, the technical features necessary for achieving this result should be added (PCT Guidelines III-4.7)

Re Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. The assessment of the claims of the present application with regard to novelty, inventive step and industrial applicability is done under the assumption that the priority of the present application is validly claimed.

2. Reference is made to the following documents:
   - **D1**: OZKER, K. S. ET AL: '99mTc labeled substance - P (SP) analogues for SP receptor imaging.' JOURNAL OF NUCLEAR MEDICINE, (MAY, 2000) VOL. 41, NO. 5 SUPPL., PP. 246P. PRINT.. MEETING INFO.: 47TH ANNUAL MEETING OF THE SOCIETY OF NUCLEAR MEDICINE. ST. LOUIS, MISSOURI, USA JUNE 03-07, 2000 SOCIETY OF NUCLEAR MEDICINE.
   - **D2**: FISCHMAN A.J. ET AL: 'A ticket to ride: Peptide radiopharmaceuticals.' JOURNAL OF NUCLEAR MEDICINE, (1993) 34/12 (2253-2263).
   - **D3**: EP-A-0 892 053

3. Novelty (Art. 33(2) PCT)

3.1. **D1** discloses a radiolabeled tachykinin peptide analogue labeled with a ^{99m}Tc isotope, for in vivo detection of SP receptor tissues (found in inflammatory diseases and neoplasms) where the linking molecule between the peptide and the isotope is a 1-imino-4-mercaptobutyl-group. In-vivo uptake in mice was shown in the salivary glands. The peptide is defined as the Substance P undecapeptide, belonging to the family of tachykinin peptides (abstract); the sequence is therefore implicitly disclosed. Since the isotope used in **D1** is the same as in the present application, the same half-life is implicitly disclosed.
D1 is therefore novelty-destroying for the subject-matter of claims 1, 2, 5-9, 12-14, 21, and 23 of the present application.

3.2. Claims 10-11, 15-20, and 22 contain novel subject-matter.

4. Inventive step (Art. 33(3) PCT)

4.1. The subject-matter of **claim 10** is not inventive, since **D2** states that ^{99m}Tc is an excellent candidate for peptide labelling, and describes bifunctional chelates employing DTPA (p. 2255, right column, 4th paragraph). Furthermore, the expert in the field is familiar with linking molecules. Therefore, the subject-matter of **claim 11** represents a mere alternative that the expert would chose without the use of inventive activity.

4.2. The subject-matter of **claims 15 and 16** is a priori not considered to be inventive the expert in the field knows the sequences of the different receptor subtypes and would be able to adapt the tachykinin analogue accordingly as well as test its affinity.

4.3. The subject-matter of **claims 17-20 and 22** is not inventive in the light of **D1**, which discloses in vivo labelling in a mouse. The expert in the field would therefore not hesitate to assume that in vivo labelling would work in any living mammalian organism.

5. Industrial applicability (Art. 33(4) PCT)

For the assessment of the present claims 12-22 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

Re Item VI

Certain documents cited

Certain published documents (Rule 70.10)

Application No Patent No	Publication date *(day/month/year)*	Filing date *(day/month/year)*	Priority date *(valid claim)* *(day/month/year)*
WO 00/50086	31.8.2000	24.2.2000	24.2.1999